

WASHINGTON STATE BOARD OF PHARMACY
MEETING AGENDA
May 17, 2007
Heathman Lodge
7801 NE Greenwood Drive
Vancouver, Washington 98662

CONVENE

Chair Rebecca Hille convened the meeting at 9:01 a.m. on May 17, 2007.

Board Members present:

Gary Harris, RPh, Vice Chair
George Roe, RPh
Rebecca Hille, Chair
Rosemarie Duffy, RN
Susan Teil-Boyer, RPh
Vandana Slatter, PharmD
Dan Connolly, RPh

Staff Members present:

Lisa Salmi, Acting Executive Director
Tim Fuller, Pharmacy Consultant
Andy Mecca, Pharmacy Consultant
Grace Cheung, Chief Investigator
Jim Doll, Pharmacist Investigator
Gail Yu, Assistant Attorney General
Doreen Beebe, Program Manager
Cheryl Christensen, Office Assistant 3

Guest(s) present:

Steve Singer, Bellegrove Pharmacy

CONSENT AGENDA:

- 1.2** Pharmacy & Other Firm Application Approval
 - Pharmaceutical Firms – New and Closed 3/13/07 thru 4/26/07
- 1.4** Pharmacy Tech Training Program Approval
 - Ilwaco, Long Beach, and Ocean Park Pharmacies
 - PIMA Medical Institute, Denver CO – Daniela Stamenova
 - Manila Central University, Manila Philippines – Gabrielle Mones
 - University of Santo Tomas, Manila Philippines – Mignonette Dael
 - Cairo University, Cairo Egypt – Adel Guirguis
 - University of the Punjab, Pakistan – Asrar Haq
 - Olympia Career Training Institute, Grand Rapids MI – Phoebe Nguyen

- 1.5 Collaborative Drug Therapy Agreement Acceptance
- Children's Hospital – Dose Rounding
 - Children's Hospital – Therapeutic Interchange
 - St John Medical Center – Heparin IV Dosing/Anticoagulation
 - St John Medical Center – Medication Refill
- 1.8 Board Minute Approval
- April 12, 2007

Items 1.1 – Pharmacist License Application Approval; 1.3 – Pharmacy Technician Application Approval; 1.6 – Automated Drug Dispensing Device Acceptance; and 1.7 – Sample Distribution Requests were deleted from the consent agenda. **ACTION:** George Roe moved that the Board approve 1.2, 1.4, 1.5 and 1.8 of the consent agenda. Gary Harris second. Susan Teil-Boyer requested 1.5 be deleted; Tim Fuller clarified the issues. Ms. Boyer then moved to approve 1.5. George Roe second. **MOTION CARRIED 6-0.**

REPORTS:

Acting Executive Director

Lisa Salmi reported:

- Received inquired from media on colchicine deaths; two patients were from Oregon and one from Washington. It appears the drug was prepared by a pharmacy in Texas and was shipped to Oregon. The drug was brought into Washington State by a relative of the deceased patient. At this time, there is no evidence that the pharmacy shipped directly to Washington State. The Annual Department of Health Board/Commission Leadership Meeting was held on May 14th. Rebecca Hille represented the Board. Topics discussed included: Interagency Guidelines on Opioid Dosing, Reorganization Update, HealthMap, Performance Guidelines, Legislative Update and the Performance Audit.
- Grace Cheung and Ms. Salmi continue to participate in the HSQA Organizational Review workgroups.
- The Quarterly Investigator meeting will be held on June 6 in Tumwater. Dan Connolly will represent the Board.
- Continue to meet with representatives of the DOH Injury Prevention Program to prepare for a briefing to Mary Selecky on strategies to reduce poisoning deaths from unintentional drug overdoses. The high risk groups include males 35-45 years of age. Washington State data and national data suggest the increase is due to intentional abuse of prescription drugs, especially with pain medications.
- The Department has contracted with Sterling Associates to conduct a workload standards study required by SHB 2974. Focus is on disciplinary activities. Goal is to develop a comprehensive and sustainable measure for allocating workload to respond to changes in case priorities. Data collection will occur during August, with the final report due in December.
- We anticipate filing the Pharmacist/Pharmacies Responsibilities rules in early June. A copy of the rules will be sent to all pharmacists and pharmacies.

- Will be attending the DEA Annual Conference on June 4-7. The agenda includes Methadone mortality, pain policy panel discussion, pharmacy theft and scheduling updates.
- The NABP Annual Meeting is May 19-22 in Portland, Oregon. Susan Teil-Boyer, Gary Harris, Rebecca Hille and George Roe will represent the Board.
- Upcoming meetings: Board/Commission/Committee – September 27-28, Renton Holiday Inn; Citizen Advocacy Center Meeting – October 31-November 2, Edgewater Hotel in Seattle.

Staffing Updates:

- Joan Benderson assumed the Credentialing Manager position effective May 7th.
- Interviews for the disciplinary support position were held on May 16th. We hope to have the position filled by June 4th.
- We are currently recruiting for four investigator positions: Central Washington, East King County, overhire and the precursor investigator. We anticipate holding interviews during the week of June 11th.
- We are re-allocating the Chief Investigator position to a Pharmacy Supervisor position to address salary disparities and anticipate opening the recruitment period in the middle of June.
- Interviews for the Executive Director position will be held on May 23rd. Rebecca Hille, Dan Connolly and George Roe are members of the interview panel.

Rebecca Hille presented plaque to Lisa Salmi in recognition of her leadership as Acting Executive Director. Lisa thanked the Board and gave recognition to staff.

Board Member Reports

George Roe attended the Oregon Society of Health-System Pharmacists in Sunriver, Oregon.

Gary Harris attended the Katterman Lecture for UW alumni pharmacists in Seattle. He informed them about the electronic newsletter and encouraged sign up.

Dan Connolly represented Bartell Drugs at a conference in Boston.

Rebecca Hille commented on administering the Oath of the Pharmacist to 96 pharmacy candidates at Washington State University. She also reported on her attendance at the DOH Leadership Meeting. The Department will have six new license credentials: registered dental assistants; licensed dental access auxiliaries; certified animal massage practitioners; licensed athletic trainers; physical therapist assistants; and veterinary technicians (credential changed from registered to licensed). Dr. Gary Franklin, Labor and Industries Medical Director, spoke on the Opioid Guidelines developed by the Agency Medical Directors Group. Dr. Franklin also shared information on the use of opioids to treat chronic pain. Laurie Jenkins gave an update on the Health Systems Quality Assurance

reorganization and the performance audit. The company conducting the audit was impressed by the cooperation of the Department.

Lisa Salmi stated that two of the new professions will be in our section; animal massage practitioners and the Veterinary Technician.

Assistant Attorney General

Gail Yu, attended on behalf of Joyce Roper. Ms. Yu had nothing to report at this time.

Consultant Pharmacist

Tim Fuller reported:

- He will be going to the Wenatchee region to make a presentation to emergency response personnel on pharmaceutical issues.
- The Emergency Response Strategic National Stockpile is still planning on its first full scale statewide exercise in Spokane later on this year in late October. He acknowledged challenges still exist in terms of logistics and recruiting volunteers.
- Attended a meeting with Nursing Quality Assurance Commission staff regarding automated distribution devices in nursing home situations. A number of issues were identified and a task force has been set up to deal with the issues.

Chief Investigator

Grace Cheung distributed copies of the Chief Investigator's report highlighting investigations and inspections for the March and April 2007 and on-going projects.

- PH:ARM Pharmaceuticals from Households: A Return Mechanism - Recently had a third burn and the project is moving forward.
- We continue to participate in the Pharm 440 classes at the University of Washington (UW) School of Pharmacy.
- Stan Jeppesen provided a lecture to the Pharmacy Communications class at the UW regarding dispensing errors.
- Bill Kristin recently taught a class in the Spokane area for technicians.
- Recognized Jim Doll for his hard work, carrying an extra load and acting in the capacity of 1.5 FTEs.
- Acknowledged that the entire investigative staff has been working hard.
- Investigator's Meetings
 - June 6/7 – Dan Connolly

- September 12/13 – George Roe
- December 5/6 – Vandana Slatter

Rebecca Hille and Dan Connolly both recognized Jim Doll's efforts and excellent work as well.

Program Manager

Doreen Beebe reported:

After the last board meeting, she contacted the WSPA and exchanged email address lists. Due to this, the electronic newsletter has over 4,800 names and addresses in the distribution list and continues to grow.

GENERAL DISCUSSION

Lisa Salmi reported that next month's budget report will show we will be overspent, but we have the revenue to cover expenses. Received approval to purchase equipment for the investigators and office equipment. Dan Connolly stated that he distributed a report on abuse of narcotics in Washington State to all of his pharmacies and feels that it should be distributed to all pharmacies and pharmacy staff in this state as well. At this time, we are not able to do so, but as the name and address data base for the electronic newsletter continues to grow, that may become a possibility. Gary Harris commented on the Katterman Lecture and suggested that the Board attend every other year.

PRESENTATIONS

Review of Pharmacy Guidelines Tim Fuller provided the Board with reference materials to aid in the discussion on the similarities and differences in Remote Order Processing; Central Fill Pharmacies; Telepharmacy Operations.

Highlights

- Central Fill Pharmacies do not provide services to walkup patients. Unless there is common ownership, the central fill pharmacy must deliver the filled prescription to the originating pharmacy.
- Remote Order Processing of medication orders does not include dispensing the prescription. Remote order processing occurs from pharmacy to pharmacy; pharmacy to pharmacist (off-site); pharmacy to hospital; hospital to pharmacist (off-site) and hospital to hospital. The remote location must have access to the information necessary or required to process a medication order. Non-resident pharmacies providing remote order processing must be licensed in Washington. Security of confidential patient information is paramount.

Question: Is a Washington pharmacist license required for non-resident pharmacists providing remote order processing from an off-site location?

Telepharmacies operate under the license of the main or central pharmacy and utilize electronic prescription transmission systems and automated drug distribution devices. The Board does not have a guideline or set of policies/procedures for telepharmacies — primary issues are around storage and recordkeeping.

ACTION: Susan Teil-Boyer moved that staff create guidelines for telepharmacy operations and appropriate changes/amendments to the central fill and remote order processing guidelines. Rosemarie Duffy second. Dan Connolly is assigned as Board Sponsor. **MOTION CARRIED 6-0.**

Rule Making Update – Placement of Carisoprodol in Schedule IV of the Uniformed Controlled Substance Act

Andy Mecca reported that as a follow-up to the March 1st stakeholder meeting an electronic request for comments was sent out on May 1st. Of the five comments the Board received three supporting the scheduling of carisoprodol based on experience. The Washington State Pharmacy Association sent notices to membership to coordinate response to the Board. WSPA received 40 comments in support and 1 opposed.

ACTION: Gary Harris moved that the Board postpone its decision on moving forward with the rules process until the next meeting to allow time to gather additional information. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

Methamphetamine Workgroup Update:

Jim Doll updated the Board on the activities of the Methamphetamine Workgroup.

The workgroup consists of two retail representatives (Dan Connolly and Lee Worthy), and representation from the Washington State Patrol (Richard Beghtol), Attorney General's office (Chris Johnson), Pierce County Prosecutor's Office (Mark Lindquist), Washington Association of Sheriffs and Police Chiefs (Scott Smith, Mountlake Terrace Police Chief), and a board appointed member (Donna Dockter). The workgroup is drafting a report due to the legislature by November 2007 to answer 5 key questions regarding the transaction logs used to capture sales of products containing ephedrine, pseudoephedrine and phenylpropanolamine (EPP) in Washington State.

1. Is the transaction log or other means of recording a transaction an effective law enforcement tool?
2. What information is needed to make logs or other means of recording a transaction a useful deterrent to criminal activity?
3. What is the most effective method of obtaining, recording, and storing log or other electronic data in the least intrusive manner available?
4. How long should the information recorded in the logs or other means of recording transactions be maintained?
5. How can logs or other means of recording a transaction be most effectively transmitted to law enforcement and the state board of pharmacy?

The transaction logs have been an effective tool. They have played a part in the significant decline on meth labs in Washington State. Has it been a deterrent? It has been a balancing act in that there has not been a decrease in the use of meth. There has been a decrease in “mom and pop” operations, however the new source of meth now seems to be Mexican meth.

Several members of the Oregon Board of Pharmacy were in attendance, including Gary Schnabel, R.N., R.Ph., Executive Director, Ann Zweber, R.Ph., Vice President and Bernie Foster, Public Member. Mr. Schnabel stated that in Oregon, pseudoephedrine is a prescription item, not over-the-counter (OTC). He also commented there has been a 95% decrease in meth labs; they went from 200 per month down to one. Resources once directed to combat the manufacturing labs and dangerous dumpsites are now directed to combat meth usage.

Mr. Schnabel stated that most people are now buying over the counter products that have been reformulated and do not contain pseudoephedrine; Oregon is seeing very few prescriptions written for the pseudoephedrine.

Jim Doll commented that Oregon’s experience is clearly related to the restrictions on pseudoephedrine sales. The Federal Drug Enforcement Administration mandated that the logs be retained for two-years, but the issue is how to effectively transmit the logs to law enforcement. In most cases, counties don’t have the staff to go from store to store to collect the data. Additional issues include legibility and completeness of the logs.

A report is being drafted to show that the vast majority of non-pharmacy shopkeepers have gotten quit selling pseudoephedrine. Out of 175 shopkeepers, 10 are still selling EPP products.

The Workgroup is considering five options to present to the legislature:

1. Make it a prescription/legend drug
2. Restrict EPP sales to pharmacy only
3. Rescind our Washington law and follow the federal mandates allowing consistency among the states
4. Require a real-time online electronic log
5. Do nothing (labs are down, the logs have worked and going electronic is expensive)

Mr. Lewis stated that labs are down approximately 80%, but Mexican meth has taken up the slack. Lisa Salmi spoke briefly about Substitute House Bill 1797 (Title of original bill: [Automating the reporting requirements for ephedrine, pseudoephedrine, and phenylpropanolamine sales by establishing a state repository](#)) sponsored by Representative Tom Campbell, who is very interested in this issue.

EXECUTIVE SESSION

The Board adjourned at 11:45 a.m. for the Executive Session to discuss personnel issues and pending litigation. The Board reconvened at 1:05 p.m. for Presentations and Discussion

PRESENTATIONS Cont’d

Bellegrove Pharmacy - The application for remote pharmacy services provided to the Stillaguamish Tribal Clinic by Bellegrove Pharmacy was approved by the board in April 2005. The Board requested a one year report following the startup of the operations. Investigators Tim Fuller, Dick Morris and Kelly McLane visited the facility a few months ago. Mr. Fuller spoke briefly regarding the inadequacy of the camera phone, and then introduced Steve Singer from Bellegrove Pharmacy for a presentation.

Steve Singer reported that their primary clients are methadone patients, but they do not dispense methadone. The pharmacy deals primarily in taking care of the other pharmaceutical needs of the patients.

Mr. Singer concurred with Tim Fuller that the videophone is inadequate and provides grainy pictures. The pharmacy is evaluating the internet and web based connections and pursuing MSN Messenger technology. The videophone has not been replaced, but they are in the process of acquiring a monitor and speakers within the next 4-6 weeks and are working on installing a webcam. He stated the phone has never really worked well, but has been adequate. There have been no dispensing errors with this operation. Before any prescription is handed out, the label and bottle are scanned, and there is an audio/visual check. A patient packet insert (PPI) is automatically printed for all new prescriptions, which accounts for 25% of all prescriptions processed. Their goal is to develop a system to provide service to significantly rural parts of the state. Dan Connolly questioned at what point do you need a pharmacist on staff and Susan Teil-Boyer was concerned with critical access. Mr. Singer stated there are areas where this type of service makes perfect sense and they are more than happy to work with Tim Fuller on this.

ACTION: Rosemarie Duffy moved to accept the report. Susan Teil-Boyer second. George Roe opposed it. **MOTION CARRIED 5-1.**

DISCUSSION

Review Enacted Legislation

Lisa Salmi reported:

- HB1103 bills did not pass. This legislation would transfer certain discipline decision making from Boards & Commissions to the Secretary.
- The Department as acquired 6 new professions, and we are getting 2 in our section
- The Prescription Monitoring Programs discussions continue
- Legislation was passed to assess health care practitioners a \$25.00 fee to support the UW Online Resource Center. Pharmacy was successful in being removed from this legislation.
- DOH will be regulating ambulatory surgical centers and establishing licensing requirements.

- Medical Quality Assurance Commission is doing a study on the source and distribution of medicinal marijuana and trying to establish what is a 60-day supply.
- The 2008 legislature is a short session and it is undecided at this point if the Department will have any request bills.

Questions from Field Investigators

Question 1

Can a pharmacy technician compound a prescription when supervised by a pharmacist?

In the Pharmacist Responsibility rules the language permits a pharmacist to allow a technician to perform bulk compounding from a formula but not pursuant to a prescription. However, the Drug Compounding Controls subsection of the Good Compounding Practices chapter suggests that a technician may compound pursuant to a prescription. This rule requires a pharmacist to check and recheck at each stage of the process to ensure each weight or measure is correct as stated in the written compounding procedures. The responsibility and accountability lies with the pharmacist.

The Board acknowledges that the Pharmacist Responsibility prohibition does not reflect current practice. **ACTION:** Vandana Slatter moved that staff develop an interpretive statement for review and approval by the Board to include definitions of supervision while we pursue the rule making process for pharmacy technicians compounding extemporaneous compounds. Susan Teil-Boyer second. **MOTION CARRIED 6-0**

Question 2

Does the ratio of one pharmacist to three pharmacy technicians still apply if the pharmacy utilizes an additional technician that is not doing technician duties?

Simply recording on the work schedule which technicians are performing non-technician duties and when would be challenging for inspectors to assess whether a pharmacy is exceeding the ratio. There is a provision in the rules where the Board may approve a pharmacy's pharmacy service plan and allow an exception to the 1 to 3 ratio. To promote public health and safety the Board believes that the 1 to 3 ratio is important. However if there is a reason that a pharmacy requires an exception to the standard ratio the pharmacy may submit a request to the Board. The Board finds that minimal overlap of the third and fourth technician meets the intent and spirit of the law.

Question 3

Can a pharmacy remain open during the prolonged absence of the pharmacist – example lunch break?

Not permitted by rule.

Request for Public Disclosure – Lists and Labels

ACTION: Gary Harris moved that the Board postpone its decision to approve or deny the public disclosure request by the Washington State Health Care Employee's Union

SEIU 1199NW until the Board's regularly appointed AAG is able to provide guidance. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

National Association of Boards of Pharmacy Proposed Resolutions

The board discussed proposed resolutions for consideration at the 103rd NABP Annual Meeting. The results are as follows:

Resolution 1:

ACTION: Rosemarie Duffy moved to accept. Susan-Teil Boyer second. **MOTION CARRIED 6-0.**

Resolution 2:

ACTION: George Roe moved to accept. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

Resolution 3:

ACTION: Rosemarie Duffy moved to accept. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

Resolution 4:

ACTION: Rosemarie Duffy moved not to accept the resolution due to lack of clarity on how pharmacists will verify bona fide patient/physician relationships. Vandana Slatter second. **MOTION CARRIED 6-0.**

Resolution 5:

ACTION: Susan Teil-Boyer moved to accept. George Roe second. **MOTION CARRIED 6-0.**

Mission Statement

The original and proposed mission statements were discussed. The proposed statement essentially divides the single sentence into two sentences. The first sentence would include the addition of the word "and." The second sentence would include the addition of "The Board of Pharmacy will educate." **ACTION:** Rosemarie Duffy moved to accept the revised mission statement. Susan Teil-Boyer second. **MOTION CARRIED 6-0.**

2008 Meeting Dates

The board discussed establishing meeting dates for 2008 and whether to hold business meetings on Friday. **ACTION:** Rosemarie Duffy moved to continue business meetings on Thursdays and disciplinary hearings on Fridays. George Roe second. **MOTION CARRIED 6-0.**

ACTION: Vandana Slatter moved to accept the 2008 dates. Rosemarie Duffy second. **MOTION CARRIED 6-0.**

ACTION: Vandana Slatter moved to accept March 5th as the planning session date. George Roe second. **MOTION CARRIED 6-0.**

Rosemarie Duffy requested recommendations on other meeting locations throughout the state.

OPEN FORUM

Doug Beeman from Group Health Cooperative addressed the Board on several issues. Washington Recovery Assistance Program for Pharmacy (WRAPP):

- Leon Alzola is the new chair for WRAPP.
- New revised brochure will be available soon.
- A WRAPP Orientation Continuing Education program has been scheduled for June 22, 2007, in the Department of Health office in Tumwater from 9:00 a.m.-noon.

PH:ARM Project:

- There have been 3 incinerations so far and it is going well. GHC is accepting medications from non-GHC subscribers as well.
- Pharmaceutical waste burn programs (similar to the Washington consumer pharmaceutical waste collection project) and discussion on possible reuse of hospice program medications were highlighted National Council of Prescription Drug Programs.

General:

- Group Health will be requesting a second license to comply with the requirements by Centers for Medicare and Medicaid Services (CMS) for its mail order pharmacy.
- Mr. Beeman has concerns that on the Department of Health's website statement of charges are listed. He has no concerns regarding the final statement of charges being listed at the conclusion of the hearing.

Mr. Beeman requested an update on the September 7, 2006, federal register of a DEA proposed rule revision on Schedule II multiple refills. Andy Mecca said he checked with the DEA a few days ago and there was no action on the proposed rule.

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Presentation of Agreed Orders

Business Meeting Adjourned

There being no further business, the Board adjourned at 4:15 p.m. The Board of Pharmacy will meet again on July 26-27 in Kent, Washington.

Respectfully Submitted by:

Cheryl Christensen, Board Staff

Approved on July 26, 2007

*Rebecca Hille, Chair
Board of Pharmacy*